REMARKS/ARGUMENTS

Claims 1-51 are pending herein, claims 1, 24, 31, 40, 43 and 49 being independent. Claim 22 has been re-written in independent form to incorporate therein the limitations of the base claim 1 from which it originally depended. Claim 3 has been amended to correct a typographical error therein. Claim 43 has been amended to clarify the terminology used therein. It is believed that the amendments made to claims 3 and 43 are cosmetic only, and do no alter the scope of those claims. New claims 52-54 have been added. No other amendment has been made to the claims, and no new matter has been added.

In the pending Office Action, the Examiner rejected claims 1-21 and 23-51 under 35 U.S.C. § 103(a) as obvious over United States Patent No. 5,779,674 (Ford), in view of United States Patent Nos. 4,952,210 (Alchas), 4,571,244 (Knighton) and 6,336,916 (Bormann, *et al.*). The Examiner objected to claim 22 as depending from a rejected base claim, but indicated that, otherwise, claim 22 presented allowable subject matter.

By the amendment above, claim 22 has been re-written in independent form, thereby placing it in condition for allowance. Early and favorable action with respect to claim 22 is therefore believed in order.

As to the obviousness rejection, applicants have carefully considered the Examiner's rejections, and the reasons offered in support thereof, but respectfully disagree with the Examiner's conclusions as to their patentability. Accordingly, for the reasons set forth in more detail below, it is submitted that the remaining claims likewise present allowable subject matter.

The following description of the invention is taken from the specification and is provided for the Examiner's convenience. It is not intended to argue limitations not present in the claims or for an interpretation of any claim term that would be more narrow than would otherwise be

ascribed to such term by one of ordinary skill in the art based upon a full and fair reading of the specification as a whole.

Claims 1-42 and 49-51

The invention is directed to the delivery of an intravenous solution to a patient. Claims 1-23 are directed to delivery systems for delivering the solution. Claims 24-30 are directed to means for self-priming such a system; claims 31-42 are directed to drip chambers for use in such a system and claims 49-51 are directed to a method for delivering the solution from the container to the patient. Claims 43-48 are discussed separately below.

Systems for delivering solutions to a patient are generally well-know. They involve providing a solution from a container to the patient through a flexible drip chamber. The drip chamber is employed so that the flow of solution may be monitored and controlled. As is well known, the container holding the solution drips the solution into the drip chamber. The faster the solution drips into the drip chamber, the faster it is dispensed to the patient. Where the solution contains medicine, the dispensing of which must be monitored over time, the rate of flow through the drip chamber may be used as a visual indicator of the rate of flow into the patient. It is therefore important that the dripping of the solution into the drip chamber be monitorable. This is especially true where the person monitoring the solution may not always be immediately adjacent to the patient, and so may have to observe the rate of dripping from a place removed from the actual patient, for example a nurse observing the rate of drip in a patient's IV from the other side of the patient's bed, from the hallway or even on a remote TV monitor at a nurse station.

At the outset of the dispensing process, the container holding the solution is attached to the drip chamber. This usually involves puncturing a valve on the container holding the solution

with a spike or other sharp implement connected to the drip chamber. The puncturing starts a flow of the solution into an empty drip chamber. To commence the flow of the solution into the drip chamber, it is necessary to "prime" the system.

Priming is conventionally accomplished by squeezing the flexible drip chamber to force air out of the drip chamber and to suction the solution into the drip chamber. Thus, the type of material useful for making drip chambers has generally been limited to flexible transparent materials that would permit priming by squeezing. Additionally, since squeezing a flexible container is not an exact science, it is possible, especially for inexperienced users, to over-fill the drip chamber, leaving an insufficient open space between the top of the drip chamber and the surface of the solution in the bottom of the drip chamber to get a clear view of the rate of drip. Furthermore, if the individual who performs the manual priming allows the dripping of the solution into the drip chamber to occur too quickly, that alone could introduce air bubbles into the solution, which bubbles would have to be removed by, for example, tapping the side of the drip chamber wall before the solution could be dispensed to the patient (*see*, *e.g.*, para. [0010] of the published application).

Once the flow of solution starts, it is restricted by a flow restrictor in the drip chamber. Before the solution is dispensed to the patient, it is allowed to accumulate in the bottom of the drip chamber to form a reservoir until it reaches a predetermined level, at which point the solution is released to the patient (what happens to the solution once it leaves the drip chamber is not presently at issue). As the drip chamber starts to fill (partially) with the solution, pressure builds up within the drip chamber unless the displaced air caused by the formation of the reservoir is allowed to vent to the surrounding atmosphere.

According to each independent claim of the invention, a vent plug or "vent" is made up of a wettable material that, when dry, allows air to flow therethrough *out of* the drip chamber, but when wetted, closes to the passage of air, and seals the drip chamber. Also according to the invention, the vent is disposed on the side of the drip chamber. This placement and configuration of the vent allows the system to self-prime without the need for "pumping" the drip chamber, and also limits the level of solution that may accumulate in the drip chamber so that the desired spacing will be preserved between the suface of the reservoir and the top of the drip chamber itself.

The combination of references applied by the Examiner fails to teach or suggest the claimed invention. It would not be obvious for one of ordinary skill in the art to combine the references in the manner suggested by the Examiner and there is no apparent reason to combine the references in the fashion suggested to result in the claimed invention.

Ford

The primary reference upon which the Examiner has relied is the Ford patent. Ford describes a fluid gas removal drip chamber for use in an IV solution delivery system. Ford's system includes a hydrophobic filter assembly **28** that allows air to pass from the interior of the drip chamber without allowing fluid to pass therethrough (col. 4, lines 53-58). Hydrophobic filter assembly **28** includes a hydrophobic membrane **52** and a support structure **53** that is disposed within membrane **28** (col. 4, lines 59-62; Fig. 2).

As seen in Fig. 2 of Ford, filter assembly **28** extends from the top of the drip chamber towards the bottom thereof (*i.e.*, towards the top of the fluid therein). The placement of filter assembly **28** would tend to obscure the dripping of the solution into the drip chamber from certain vantage points (*e.g.*, from the right side as viewed in Fig. 2), which will obscure visual

inspection as well as electronic/optical inspection such as in the case where an electronic drip monitor is employed. Ford teaches that hydrophobic filter assembly **28** must be "vertical" (which includes an angled presentation), but "not an entirely horizontal hydrophobic membrane" (col. 7, lines 7-18).

Alchas

The Alchas patent is directed to a parenteral fluid administration set that includes a vented container assembly **50** having housing **51** and a chamber **52** for retaining fluid therein. Housing **51** includes a venting means having an aperture **58** covered by an air-permeable, liquid-impermeable element **59** (col. 6, line 53 – col. 7, line 3). Element **59** allows air to enter chamber **52** while preventing liquid from flowing either way therethrough. There is no discussion in Alchas of having the properties of element **59** vary when it is wetted.

Container assembly **50** dispenses the solution to be introduced to the patient into an unvented drip chamber **103** by squeezing of the flexible drip chamber (Figs. 8 and 14, *inter alia* – "Also, the squeezing force is repeated to start the flow of fluid from the vented container into the drip chamber as best illustrated in Fig. **14**."; col. 12, lines 33-36). Drip chamber **103** has no vent in it whatsoever.

Bormann, *et al.*

The Bormann, *et al.* patent is directed to a priming system for the administration of parenteral fluids. Bormann, *et al.* teach the importance of providing for the venting of gas from a drip chamber to provide for ease of monitoring, *etc.* (*see*, generally, col. 1, lines 31-67). The Borrman, *et al.* system uses a vent **3** located in the top of the device **100**. Vent **3** preferably includes a porous medium **10** that includes both liquophobic and liquophilic elements or layers

(col. 5, line 62 – col. 6, line 9). Vent 3 allows the passage of air therethrough until it is wetted, at which point it seals device **100** (col. 6, lines 14-17).

There is no apparent reason to one of ordinary skill in the art to combine the references in the fashion suggested by the Examiner.

The applied references are all generally directed to the same art as is the present invention, and yet they each take an approach that differs markedly from one another, and are inconsistent in their approaches so that one of ordinary skill in the art would not combine them.

Ford and Bormann, *et al.*, for example, teach that the vent in the drip chamber must be on the top of the chamber, *not* on the side as claimed. The Examiner apparently concedes this point, as it is Alchas' disclosure that the Examiner uses to show the venting on the side of the drip chamber (Office Action, p. 4). However, Alchas' aperture **58** (which the Examiner has likened to the claimed vent in the side of the drip chamber) is not in the drip chamber at all, rather it is in the container *above* the drip chamber. Additionally, the vent in Alchas is intended to allow air to *enter* the container, rather than leave it (col. 7, lines 59-63), and so it's the precise opposite of the claimed invention for this reason, as well.

The Examiner, without support, however, states that one of ordinary skill in the art would have found it obvious to move "the vent of Ford on the side of the drip chamber". As noted above, Ford *expressly* teaches that the vent must be vertical, and *cannot be horizontal* (Ford, col. 7, line 15-17). The Examiner provides no basis for arguing that one of ordinary skill in the art could be motivated to modify Ford in a manner *completely inconsistent with and directly opposite to* the express teachings of Ford to move the vent to the side of the drip chamber to allow air to exit the drip chamber, based on a teaching from another patent that a vent *in another element of the system* could be on the side of that element to let air *in*. There is no teaching in

either patent that a vent could be placed on the side of the drip chamber to let air *out*, and so it is submitted that no one of ordinary skill in the art could combine the references *and modify that combination* to provide one. The Examiner has pointed to nothing in the record to support such a radical modification.

Furthermore, Ford expressly teaches that the vent be made of a hydrophobic material. The Examiner argues that Bormann, *et al.* teach that the vent could be made of a wettable material (which is partly hydrophilic), but makes no showing why one of ordinary skill in the art would modify Ford *in a manner completely inconsistent with Ford's teachings* to adopt some of the teachings of Bormann, *et al.*

The combination of references, even if made, would not lead one of ordinary skill in the art to the claimed invention.

As shown, no reference applied by the Examiner shows the use of a horizontal vent on the side of the drip chamber to let air out, and so no possible combination of those references could be cobbled together, in a manner consistent with the teachings of the references themselves, to teach that limitation of the claims.

In addition, no reference shows the placement of a vent on the side of the drip chamber (or anywhere else) to limit the amount of solution that passes into the drip chamber and thereby prevent the raising of the level of solution to the height of the vent. The sole reference that the Examiner applies for teaching the use of a side vent, Alchas (which, as noted does not show the placement of a vent in the drip chamber at all), shows that the level of the solution in chamber **52** may be well above the level of aperture **58** (*see*, Fig. 5). Thus, there is no teaching of this claim limitation in the references, taken in *any* combination, either.

Claims 43-48, 52 (new) and 53 (new)

Claims 43-48, 52 and 53 are directed to a solution delivery system for delivering a solution to a patient. The system of these claims includes a conduit for conducting the solution to the patient and means for regulating the flow of fluid through the conduit to the patient. The inventive system further includes a termination end cap which has a vent and a vent plug. The vent, when unplugged, allows entrapped air to pass therethrough, but is sealed when wetted.

When initiating the delivery of a solution to a patient through a conduit, the conduit starts out empty, *i.e.*, containing only air. This air must be purged before connecting the conduit to the patient, or else the air in the conduit would cause an embolism in the patient. According to the invention, the air may be purged automatically by use of the wettable sealing material in the vent claimed in claims 43-48, 52 and 53.

As claimed, the inventive system has a termination end cap at the termination end of the conduit. The termination end cap includes a valve of a wettable material that allows gas (e.g. air, etc.) to pass therethough when dry, and seals off to prevent the passage therethrough of a liquid when the wettable material is wetted. With this structure, the inventive system may automatically self-purge the entrapped air in the conduit through the vent when use is initiated, and then seal the vent when the last of the gas is purged. This structure is nowhere shown, taught or suggested in the applied references.

The structure of the system claimed in claims 43-48, and particularly in new claims 52 and 53, allows for the venting rate of the system to be brought into balance automatically, *i.e.*, the termination end cap (claim 53) allows for the simultaneous and automatic purging of entrapped air from the conduit and creating of the reservoir in the drip chamber, while avoiding the introduction of air into the conduit. The structure as claimed in this system allows for this benefit, which had heretofore been unrealized in the art.

The Examiner has likened the drip chamber of Ford to the claimed flow regulator, and taken the position that "it would have been obvious to one of ordinary skill in the art to include a vent in the end cap so that air may escape until it is wetted" (Office Action, p. 24). However, the Examiner overlooks the requirement that the vent be in the "termination end" of the conduit. In Ford, the air vent is in the top of the drip chamber, which is on the end of the drip chamber *opposite* to the termination end thereof, *i.e.*, opposite to the bottom of the drip chamber. No reference applied by the Examiner shows the use of a vent at the bottom or end of the system, since the vents of the references applied by the Examiner universally are used to regulate the passage of air at the opposite end of the flow of liquid, *not at the **termination** end thereof.* The Examiner has not made any showing of why it would be reasonable for one of ordinary skill in the art to alter the references or combine the references in such as a way as to be inconsistent with all of the references, and to contradict the one feature that is common to all of these references, namely that the vent is positioned at a location in the system distant from the patient and not at the termination end.

It is therefore respectfully submitted that the combination of references applied by the Examiner fails to teach or suggest the invention of claims 43-48. Withdrawal of this rejection is believed to be in order.

For all these reasons, therefore, the references taken alone or in any combination cannot be combined to result in the claimed invention.

There being no further grounds for objection or rejection, early and favorable action is respectfully solicited.

The fee of $150.00 for the addition of thee new claims in excess of twenty and the fee of $210.00 for the addition of one new independent claim in excess of three, together with the fee

of $120.00 for a one-month extension of time and the fee of $180.00 for the filing of an Information Disclosure Statement are enclosed. It is believed that no further fees are required. However, in the event any further fees are required, please charge the undersigned's Deposit Account No. 03-2412. Likewise, in the event of any overpayment, please credit that deposit Account.

Respectfully submitted,
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